

Notice of Allowability

Application No.

10/634,862

Examiner

Mary E. Mosher, Ph.D.

Applicant(s)

RUDERT ET AL.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to telephonic discussion of 8/3/05 & 8/8/05.
2. ☒ The allowed claim(s) is/are 1,16,27,33,36-45,50 and 51.
3. ☒ The drawings filed on 06 August 2003 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/495880.
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>8/6/03</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

T.D

EXAMINER'S AMENDMENT

An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment which places this application in condition for allowance. During a telephone conversation conducted on August 3 and 8, 2005, Steve Yoder and Paul Booth requested an extension of time for tow additional MONTH(S) and authorized the Director to charge Deposit Account No. 08-1841 the required fee of \$900 (\$1020 - \$120 previously paid) for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

The claims have been amended as shown on the attached listing of all claims.


The specification has been amended as shown on the attached pages.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

8/8/05


MARY E. MOSHER, PH.D.
PRIMARY EXAMINER

Claim listing

1. (Currently Amended) A filamentous polyphage particle which
 - (a) contains
 - (i) a first recombinant vector molecule that comprises a nucleic acid sequence, which encodes a fusion protein of a first member of a multimeric (poly)peptide complex fused to at least part of a filamentous phage coat protein, and that carries or encodes a first selectable and/or screenable property, and
 - (ii) a second recombinant vector molecule that comprises a nucleic acid sequence, which encodes a second member of a multimeric (poly)peptide complex, and that carries or encodes a second selectable and/or screenable property different from said first property; and
 - (b) displays said multimeric (poly)peptide complex at its surface.

Claims 2-15 (canceled).

16. (Previously presented) The particle of claim 1, wherein said first vector is a phage vector and said second vector is a phagemid vector.

17. (Previously presented) The particle of claim 1, wherein said first and second vectors are phagemid vectors.

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18. (Previously presented) The particle of claim 17, wherein said two phagemid vectors are compatible.

19. (Previously presented) The particle of claim 17, wherein (i) said first phagemid vector comprises a Co1E1 origin of replication and said second phagemid vector comprises a p15A plasmid origin of replication; or (ii) said first phagemid vector comprises a p15A origin of replication and said second phagemid vector comprises a Co1E1 plasmid origin of replication.

20. (Currently amended) The particle of claim 17, wherein (i) said first phagemid vector comprises a Co1E1 origin of replication and said second phagemid vector comprises a mutated Co1E1 origin of replication, wherein said mutated Co1E1 origin of replication renders said second phagemid vector compatible with said first phagemid vector; or (ii) said first phagemid vector comprises a mutated Co1E1 origin of replication and said second phagemid vector comprises a Co1E1 plasmid origin of replication, wherein said mutated Co1E1 origin of replication renders said first phagemid vector compatible with said second phagemid vector.

21. (Previously presented) The particle of claim 1, wherein said vectors comprise different phage origins of replication.

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22. (Previously presented) The particle of claim 1 wherein said vectors are interference resistant.

23. (Previously presented) The particle of claim 1, wherein at least one of said vectors is a phage or phagemid vector having one or more mutations in the phage intergenic regions) and/or in gene II.

24. (Currently amended) The particle of claim 1, wherein at least one of said vectors is a phage or phagemid vector that is (i) an IR1 mutant or an IR2 mutant and (ii) interference resistant.

25. (Currently amended) The particle of claim 1 wherein at least one of said vectors first and second vector molecules is (i) a phage or phagemid vector comprising a hybrid nucleic acid sequence of f1-, fd-, and/or M13-mutated derived sequences, and (ii) interference resistant.

26. (Currently amended) The particle of claim 16, wherein said vector is SEQ ID NO: 31 ~~or a mutant thereof.~~

27. (Currently amended) The particle of claim ~~26~~ 16, wherein said phage vector is a mutant derived from SEQ ID NO:31 comprising the phage origin of replication from

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fpep3_IB-IRseq, the gene II from fpep3-IB-IRseq, or a combination of said phage origin of replication and said gene II.

Claims 28-32 (Canceled).

33. (Currently amended) The particle of claim 1, wherein any of said vectors that contains the gene VII contains an amber mutation in said gene VII.

Claims 34-35 (Canceled).

36. (Previously presented) The particle of claim 1, wherein said phage coat protein is gIIIp or gVIIIp.

37. (Previously presented) The particle of claim 1, wherein said phage particle is infectious by having a full-length copy of gIIIp.

38. (Previously presented) The particle of claim 1, wherein said phage particles are non-infectious by having no full-length copy of gIIIp, said fusion protein being formed with a truncated version of gIIIp, wherein the infectivity can be restored by interaction of the displayed multimeric polypeptide complexes with a corresponding partner coupled to an infectivity-mediating particle.

39. (Previously presented) The particle of claim 38, wherein said truncated gIIIp comprises the C- terminal domain of gIIIp.

40. (Currently amended) The particle of claim 39, wherein said truncated gIIIp is a ~~mutant~~ derivative of phage fCA55, wherein said derivative leads to the formation of polyphages.

41. (Previously presented) The particle of claim 1, wherein said multimeric polypeptide complex is a functional fragment of an immunoglobulin.

42. (Previously presented) The particle of claim 41, wherein said fragment is an Fv, dsFv or Fab functional fragment.

43. (Currently amended) The particle of claim 1, wherein said first and/or said second selectable and/or screenable property is the ~~transactivation~~ of transcription of (i) a reporter gene selected from the group consisting of beta-galactosidase and alkaline phosphatase; or (ii) a nutritional marker selected from the group consisting of his3 and leu; or (iii) a resistance gene giving resistance to an antibiotic selected from the group consisting of ampicillin, chloramphenicol, kanamycin, zeocin, neomycin, tetracycline and streptomycin.

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44. (Previously presented) The particle of claim 23, wherein the mutation is in the phage intergenic region corresponding to position 5986 of f1.

45. (Previously presented) The particle of claim 23, wherein the mutation is in gene II corresponding to position 143 of f1.

46-49 (Canceled).

50. (new) The particle of claim 27, wherein said mutant comprises fd/f1 origin including mutation G5737>A (2976 in fpep3_1B-IR3seq), and/or the mutations G343>A (3989 in g II, and G601>T (4247) in g II/X.

51. (new) The particle of claim 16, wherein said phagemid vector comprises the phage origin of replication from fpep3_1B-IRseq, the gene II from fpep3_1B-IRseq, or a combination of said phage origin of replication and said gene II.

In the Specification

On the first page, after the title and before Background Of the Invention, please delete the paragraph presented in the Amendment filed November 15, 2004 and replace it with the following paragraph:

This application is a Divisional of U.S. Serial No. 09/495,880 filed February 1, 2001, now Patent No. 6,667,150, which is a continuation of International Application PCT/EP98/04836, filed August 3, 1998. Application Serial No. 09/495,880 is incorporated herein in its entirety by reference hereto.

On page 20, second paragraph, please replace the material mistakenly added in the amendment filed November 15, 2004, with the material mistakenly deleted:

To prove that only the correct phage vector is present in SIP polyphage transductants, DNA of positive (fpep3_1B-IR3seq3/ pIG10.3-IMPp75) and negative (fjun_1B-IR3/ pIG10.3-IMPp75) control co-transformants, as well as DNA from the SIP polyphage transductants derived from SIP phages produced by the mix of positive and negative control bacteria was analyzed by PCR (Fig. 8). Primers FR614 (5'-GCTCTAGATAACGAGGGC-3' (SEQ ID NO 49)) and FR627 (5'-CGCAAGCTTAAGACTCCTTATTACGC-3' (SEQ ID NO 50)) amplify the phage region from the start of ompA to the end of gIII. PCR products derived from fpep3_1B-IR3seq3 and fjun_1B-IR3 can be discriminated by size. Gel analysis of the above samples verified that only the expected fpep3_1B-IR3seq3 phage was present in SIP polyphage transductants (6 analyzed).

In addition, on specification page 14, replace the paragraphs on lines 8-10 with:

Figure 2: Functional map and sequence of phage vector fhag1A (SEQ ID NO: 3)

Figure 3: Functional map and sequence of phage vector fjun_1B (SEQ ID NO: 18)

Figure 4: Functional map and sequence of phage vector fpep3_1B-IR3seq (SEQ ID NO: 31)